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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,264	09/16/2003	Nicholas W. Warne	22058-544 (AM100664)	1450

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EXAMINER

HISSONG, BRUCE D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,264	Applicant(s) WARNE ET AL.	
	Examiner Bruce D. Hissong	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/1/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

A. Formal matters

1. The Examiner notes that claim 9 is self-referential. For the purpose of this Office Action, claim 9 has been interpreted as depending from claim 5.

B. Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-4, 13-15, drawn to a pharmaceutical composition comprised of a bioactive peptide, classified in class 514, subclass 2.
2. Claims 5-12, 16-26, drawn to a pharmaceutical composition comprised of an interleukin-11 (IL-11) peptide, classified in class 424, subclass 85.2.
3. Claim 27, drawn to a pharmaceutical composition comprising a bioactive peptide enveloped by a sealing coat, an enteric coating layer, and a second sealing coat, classified in class 514, subclass 2.
4. Claims 28-41, drawn to a pharmaceutical composition comprising an IL-11 peptide enveloped by a sealing coat, an enteric coating layer, and a second sealing coat, classified in class 424, subclass 85.2.
5. Claim 42, drawn to a method of delivering a bioactive peptide, classified in class 514, subclass 2.
6. Claims 43-47, drawn to a method of delivering an IL-11 peptide, classified in class 424, subclass 85.2.
7. Claims 48-52, drawn to a method of treating inflammatory bowel disease, classified in class 424, subclass 85.2.

C. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 are independent and distinct inventions, each from the other, because they are products that possess characteristic differences in structure and function, and each has a distinct and independent utility. The invention of group 2 is an IL-11 peptide, which differs in both structure and function from the bioactive peptide of group 1, and has separate utility as a therapeutic agent for hematopoietic disorders. Similarly, the invention of group 4 differs in both structure and function from the invention of group 3, for the same reasons stated above. The inventions of groups 3 and 4 differ in both structure and function from the inventions of groups 1 and 2 because they comprise compositions having sealing coats and enteric coating layers.

Inventions 1, 3 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the invention of groups 1 and 3 can be used in a materially different process from that of group 5, such as a method of treatment for a disease.

Inventions 2, 4 and 6, 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inventions of groups 2 and 4 can be used in a materially different process from that of group 6, including intravenous administration or oral delivery in liquid form. The invention of group 7 can be practiced with another materially different product, such as anti-TNF α antibodies.

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Inventions 1, 3 and 6, 7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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Inventions 2⁴ and 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions 5-7 are independent and distinct inventions, each from the other, because the methods are practiced with materially different process steps for materially different purposes, and each method requires a non-coextensive search because of different starting materials, process steps, and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Bruce D. Hissong, Ph.D.**, whose telephone number is **(571) 272-3324**. The examiner can normally be reached on 8:30am - 5:00 pm. If attempts to reach the examiner

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by telephone are unsuccessful, the examiner's supervisor, **Anthony Caputa, Ph.D.**, can be reached on **(571) 272-0829**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER